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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,469	04/21/2004	Michael D. Laufer	100873-273 (END6430USCNT8)	5223
81353                      7590                      11/04/2008 Ethicon Endo-Surgery/Nutter, McClennen & Fish LLP World Trade Center West 155 Seaport Blvd. Boston, MA 02210-2604				
EXAMINER WOO, JULLAN W				
ART UNIT 3773		PAPER NUMBER		
NOTIFICATION DATE 11/04/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

### Office Action Summary

**Application No.**

10/828,469

**Applicant(s)**

LAUFER ET AL.

**Examiner**

Julian W. Woo

**Art Unit**

3773

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48-62 and 64-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-62 and 64-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)  
Paper No(s)/Mail Date 7/24/08, 8/6/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Objections***

1. Claims 69-159 are objected to because of the following informality: The status of these claims is not shown in the listing of claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 48-62 and 64-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (5,403,326) in view of Kortenbach (6,312,437). Harrison et al. disclose the invention substantially as claimed. Harrison et al. disclose, at least in figures 8C and 8D and in col. 8, lines 23-30; a method, with respect to claims 48-52, including piercing the stomach tissue with a piercing member (at least one of the jaws (at 90)), where one jaw includes an implant that pierces tissue (90), where one jaw

includes a tissue piercing element (94) that delivers at least a portion of an implant (92), where the jaws are configured to deploy an implant into the stomach tissue (96 and/or 90), where engaging stomach tissue includes placing parts of a tissue fixation device (72) coupled to the jaws in contact with the stomach tissue. With respect to claims 53-62 and 64-68, Harrison et al. also disclose a method of treatment including piercing the stomach tissue with a piercing member (94), engaging stomach tissue with a plurality of members (66) from within the stomach, and moving at least one of the plurality of members to place exterior surface regions of the stomach in apposition (with an esophagus or near the gastroesophageal junction), where the method includes fixing the exterior surface regions of the stomach to each other (i.e., at least the regions between elements 94 that are inherently pressed together when elements 94 pierce and displace stomach tissue), where fixing includes placing at least one tissue fixation device (94 with respect to claims 56 and 57) through at least one full-thickness layer of the stomach, where engaging includes pulling the stomach tissue into a tissue securing device (72), where engaging includes applying pressure to the stomach tissue (from movement of jaws 66 toward each other), and where securing the exterior surface regions includes using the tissue securing device (which fixes the positions of the regions with respect to each other and to the esophagus).

However, Harrison et al. do not disclose engaging the pierced stomach tissue with a pair of coacting jaws or at least one of a plurality of members from within the stomach, and piercing the stomach tissue (again) with at least one of the jaws. Kortenbach teaches, at least in figures 11-15 and col. 8, line 36 to col. 9, line 2;

engaging pierced stomach tissue (i.e., stomach tissue pierced with element 46) with a pair of coacting jaws (31, 40) or members, repositioning the coacting jaws or members for engaging another portion of stomach tissue, and piercing the stomach tissue (again) with element 46 from jaw or member 40. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kortenbach, to modify the method of Harrison et al., to engage the pierced stomach tissue with a pair of coacting jaws (66) or at least one of a plurality of members from within the stomach, and piercing the stomach tissue (again) with at least one of the jaws or members (at 90). Such a modification would ensure that the desired fundoplication is achieved.

#### ***Response to Amendment***

4. Applicant's arguments with respect to claims 48-62 and 64-68 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

November 1, 2008